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(54) **VACUUM WOUND CARE MODULE**

(57) A vacuum wound care module comprising: a fluid reservoir (251); a pump module (252) fluidly connected to the irrigation reservoir (251) and adapted for pumping fluid out of the fluid reservoir (251); a venturi vacuum (253) fitting fluidly connected to the pump module (252) and having a vacuum outlet (253C) and a fluid outlet (253B); a fluid connection (263, 264) from the fluid outlet (253C) to the fluid reservoir (251); a trap reservoir (255) fluidly connected to the vacuum outlet (253C); and a second fluid connection (121) that is one of: (a) fluidly connected to the trap reservoir (255) and (i) adapted to be fitted with a wound dressing to provide vacuum and allow removal of wound exudate or (ii) fitted to such a wound dressing such that, when the wound dressing is employed, it provides vacuum and allows removal of wound exudate, and (b) adapted to be fluidly connected to the trap reservoir (255) and fitted to such a wound dressing such that, when the wound dressing is employed, it provides vacuum and allows removal of wound exudate.

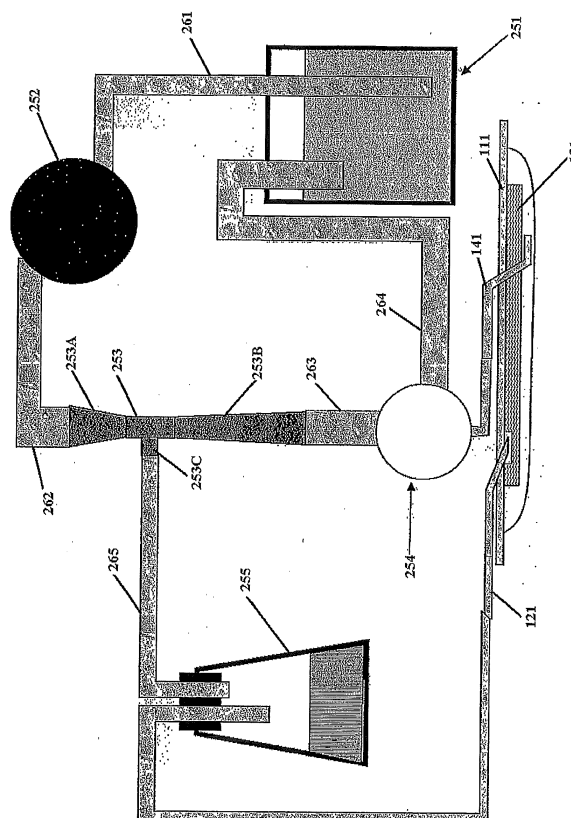


Fig. 4

Description

[0001] This application claims the priority of U.S. Provisional Application No. 60/625,488, filed November 5, 2004.

[0002] The present invention relates to methods, devices and kits for treating a wound with a dressing and vacuum.

[0003] Vacuum has been used to increase blood flow to wound tissue and to remove exudate from the wound site. It is believed that it has not been recognized that such methods can be effectively combined with gel-forming wound care products placed against the wound to which vacuum is applied.

Summary of the Invention

[0004] Provided, in one embodiment, is a vacuum wound dressing for covering a wound bed comprising: a wound contact layer comprising a fibrous blend or fibrous material that forms a cohesive gel when wetted by wound exudate; a source of vacuum situated to be separated from the wound bed by the wound contact layer; and a vacuum sealing layer covering the wound contact layer and adapted to retain relative vacuum in the wound contact layer, wherein (i) the dressing is essentially missing a non-gelling, foam layer in which the source of vacuum is situated or (ii) the vacuum sealing layer comprises as an outer layer a foam layer.

[0005] Provided, in another embodiment, is a vacuum wound care module comprising: an fluid reservoir; a pump module fluidly connected to the irrigation reservoir and adapted for pumping fluid out of the fluid reservoir; a venturi vacuum fitting fluidly connected to the pump module and having a vacuum outlet and a fluid outlet; a fluid connection from the fluid outlet to the fluid reservoir; a trap reservoir fluidly connected to the vacuum outlet; and a second fluid connection that is (i) adapted to be fitted with a wound dressing to provide vacuum and allow removal of wound exudate or (ii) fitted to such a wound dressing such that, when the wound dressing is employed, it provides vacuum and allows removal of wound exudate.

Brief Description of the Drawings

[0006]

Figure 1a shows a top view of separated products used in an illustrative embodiment of the invention.

Figure 1b shows a side view of the illustrative embodiment.

Figure 2 illustrates a side view of another illustrative embodiment.

Figure 3 illustrates a composite of a wound care product similar to that of **Figures 1a** and **1b**, but further including a source of irrigation fluid.

Figure 4 illustrates a vacuum device for use in wound

care.

Detailed Description of the Invention

[0007] The outer dressing used in the vacuum method can include a vacuum sealing outer layer that is film layer **11**, and a foam layer **12**. As illustrated in **Figs. 1a** and **1b**, a vacuum source connector **21** (e.g. silicone tubing) can be slotted through film layer **11** and foam layer **12**, and sealed with another adhesive film **41**. Film **41** can be, for example, the Opsite™ film dressing from Smith & Nephew (Cambridge, United Kingdom). The vacuum permeable foam layer **12** is separated from direct contact with the wound by wound contact layer **31**.

[0008] As illustrated, the source of vacuum (illustrated as tubing) is favorably separated from the wound by a wound contact layer, or a portion of a wound contact layer.

[0009] As illustrated in **Figure 2**, the outer layer of the vacuum sealing layer can be foam layer **312**, with the porosity of the foam layer selected to retain a portion of the vacuum at the wound site. Foam layer **312** is separated from direct contact with the wound by wound contact layer **331**. Vacuum source connector **321** can be slotted through foam layer **312**.

[0010] The vacuum sealing layer can be, for example, a film layer alone (see **Fig. 3**, discussed below), or a foam layer alone (see **Fig. 2**).

[0011] A foam layer can be provided by the foam layer of the Versiva® dressing available from ConvaTec (Skillman, NJ).

[0012] The wound contact layer is, for example, a fibrous blend or fibrous material (e.g., non-woven) that forms a cohesive gel when wetted with wound exudate. Such a fibrous material can be provided, for example, by the wound contact layer of the Versiva® dressing (ConvaTec, Skillman, NJ) or by a fibrous mat of sodium carboxymethylcellulose. A fibrous mat of sodium carboxymethylcellulose is available as AQUACEL® dressing from ConvaTec, as is a similar dressing further including silver. Other exemplary wound contact layers are provided by Medigel™, Carboflex™ (which provides an odor absorbent layer with fibrous material for wicking liquid away from the odor absorbent), Hyalofill™ (forming a hyaluronic acid-rich fibrous gel) or Kaltostat™ (containing alginate) dressings from ConvaTec.

[0013] The vacuum sealing layer serves to limit loss of reduced pressure such that a therapeutically useful degree of reduced pressure pertains at the wound site. Loss of reduced pressure (through the vacuum sealing layer) can be significant if compensated by the source of vacuum. It will be recognized the "vacuum" refers to reduced pressure relative to atmospheric pressure. The vacuum source provides a sufficient reduction in pressure such that a therapeutically useful degree of reduced pressure pertains at the wound site.

[0014] The wound contact layer can be selected to be effective to adhere the dressing to the wound site, even

in the absence of vacuum, and to retain adhesiveness even as it is saturated with exudate liquid. Or, adhesion can be provided at the peripheries of the wound dressing.

[0015] As illustrated in **Figure 3**, the vacuum wound dressing can be used with a fluid source connector **141** (here illustrated as a tube). The fluid can be, for example, an irrigating fluid, such as saline or a saline substitute, and can include an anti-infective. The irrigating fluid can be pumped to the wound bed, or drawn by the relative vacuum conveyed by vacuum source connector **121** (and sufficiently retained by vacuum sealing layer **111**).

[0016] In certain embodiments, the wound care dressing(s) used with vacuum provide vacuum sealing layers with maximum pores of greater than **100** micron pore size.

[0017] As illustrated in **Figure 4**, a vacuum wound care module can be used to provide vacuum and, optionally, irrigation fluid to a wound. The module can be scaled as a bedside unit, or miniaturized such that it can, for example, be adhered or otherwise affixed near the wound site on a patient. In the illustrated embodiment, there are a reservoir **251**, pump module **252**, venturi vacuum unit **253**, optional diverting valve **254**, and trap reservoir **255**. Fluid connectors **261**, **262**, **263**, **264** and **265**, vacuum source connector **121**, and fluid source connector **141** make fluid connections as illustrated. The reservoir **251** provides fluid (i) to move through the venturi vacuum unit **253** to generate vacuum and (ii), optionally, provide irrigating fluid for the wound. If the fluid of the reservoir **251** is to provide irrigating fluid, the fluid is physiological saline or saline substitute suitable for irrigating a wound.

[0018] The pump module **252** can be the mechanical pieces that provide pumping, with or without the components that provide motive force or pumping. For example, the pump module **252** can be adapted to couple with a motor to activate the pump parts, or the pump module **252** can be adapted to be engaged by external electro-magnet(s) to activate the pump parts. The venturi vacuum unit **253** will typically have a region in which its internal diameter expands to increase the speed of fluid flow (from the inlet **253A** to the fluid outlet **253B**), thereby reducing pressure according to Bernoulli's Principle and providing vacuum at vacuum outlet **253C**.

[0019] Optional diverting valve **254** typically has two operating positions, each adapted to allow flow in the "pump circuit" from the reservoir, through the venturi vacuum unit, and returning to the reservoir. One of the operating positions additionally diverts an amount of flow suitable to provide irrigation fluid to the wound. To at least a certain extent, back pressure from the flow pathway to the wound can help regulate the rate of this diverted flow.

[0020] Trap reservoir **255** is situated to collect wound exudate and used irrigating fluid before the vacuum draws such spent fluid into the pump circuit. Additional trap reservoirs, and/or sterile filters, can be placed to limit any potential contamination of the pump circuit. The various fluid conduits of the vacuum wound care module can incorporate check valves to help assure that there

is no significant flow in an unintended direction. For example, such check valves can prevent flow of reservoir fluid out the vacuum outlet **253C** should the pump circuit be temporarily blocked, such as when the diverting valve is switched from one position to the other.

Definitions

[0021] The following terms shall have, for the purposes of this application, the respective meanings set forth below.

• non-gelling, foam

[0022] A non-gelling, foam is a material that does not gel to a functionally significant extent, and is sufficiently porous to move fluid by capillary action.

[0023] Publications and references, including but not limited to patents and patent applications, cited in this specification are herein incorporated by reference in their entirety in the entire portion cited as if each individual publication or reference were specifically and individually indicated to be incorporated by reference herein as being fully set forth. Any patent application to which this application claims priority is also incorporated by reference herein in the manner described above for publications and references.

[0024] While this invention has been described with an emphasis upon preferred embodiments, it will be obvious to those of ordinary skill in the art that variations in the preferred devices and methods may be used and that it is intended that the invention may be practiced otherwise than as specifically described herein. Accordingly, this invention includes all modifications encompassed within the spirit and scope of the invention as defined by the text in the Figures.

[0025] Certain definitions of the invention are set forth in the following clauses:

CLAUSES

[0026]

1. A vacuum wound care module comprising:

- a fluid reservoir;
- a pump module fluidly connected to the irrigation reservoir and adapted for pumping fluid out of the fluid reservoir;
- a venturi vacuum fitting fluidly connected to the pump module and having a vacuum outlet and a fluid outlet;
- a fluid connection from the fluid outlet to the fluid reservoir;
- a trap reservoir fluidly connected to the vacuum outlet; and
- a second fluid connection that is one of:

(a) fluidly connected to the trap reservoir and (i) adapted to be fitted with a wound dressing to provide vacuum and allow removal of wound exudate or (ii) fitted to such a wound dressing such that, when the wound dressing is employed, it provides vacuum and allows removal of wound exudate, and

(b) adapted to be fluidly connected to the trap reservoir and fitted to such a wound dressing such that, when the wound dressing is employed,

it provides vacuum and allows removal of wound exudate.

2. The vacuum wound care module of CLAUSE 1, wherein the second fluid connection is according to (a).

3. The vacuum wound care module of CLAUSE 1, wherein the second fluid connection is according to (b).

4. The vacuum wound care module of CLAUSE 1, further comprising:

a diverting valve situated in the first fluid connection, the valve operating between (i) a position that directs fluid from the fluid outlet and the fluid reservoir and (ii) a position that directs a major portion of fluid from the fluid outlet and the fluid reservoir and a minor portion to a third fluid connection; and the third fluid connection that is one of

(A) fluidly connected to the diverting valve and (i) adapted to be fitted with a wound dressing to provide fluid to the wound or (ii) fitted to such a wound dressing such that, when the wound dressing is employed, it provides such fluid, and

(B) adapted to be fluidly connected to the diverting valve and fitted to such a wound dressing such that, when the wound dressing is employed, it provides such fluid.

5. The vacuum wound care module of CLAUSE 4, wherein the third fluid connection is according to (A).

6. The vacuum wound care module of CLAUSE 4, wherein the third fluid connection is according to (B).

7. A vacuum wound dressing for covering a wound bed comprising:

a wound contact layer comprising a fibrous blend or fibrous material that forms a cohesive

gel when wetted by wound exudate;

a source of vacuum situated to be separated from the wound bed by the wound contact layer; and

a vacuum sealing layer covering the wound contact layer and adapted to retain relative vacuum in the wound contact layer, wherein (i) the dressing is essentially missing a non-gelling, foam layer in which the source of vacuum is situated or (ii) the vacuum sealing layer comprises as an outer layer a foam layer.

8. The vacuum wound dressing of CLAUSE 1, further comprising:

a source of irrigating fluid situated to deliver irrigating fluid to the wound bed.

9. The vacuum wound dressing of CLAUSE 1, wherein (i) the dressing is essentially missing a non-gelling, foam layer in which the source of vacuum is situated.

10. The vacuum wound dressing of CLAUSE 9, further comprising:

a source of irrigating fluid situated to deliver irrigating fluid to the wound bed.

11. The vacuum wound dressing of CLAUSE 1, wherein (ii) the vacuum sealing layer comprises as an outer layer a foam layer.

12. The vacuum wound dressing of CLAUSE 11, further comprising:

a source of irrigating fluid situated to deliver irrigating fluid to the wound bed.

Claims

1. A vacuum wound dressing for covering a wound bed comprising:

a wound contact layer comprising a fibrous blend or fibrous material that forms a cohesive gel when wetted by wound exudate; a source of vacuum situated to be separated from the wound bed by the wound contact layer; and

a vacuum sealing layer covering the wound contact layer and adapted to retain relative vacuum in the wound contact layer, wherein the dressing is essentially missing a non-gelling, foam layer in which the source of vacuum is situated.

2. The vacuum wound dressing of claim 1, further comprising:

a source of irrigating fluid situated to deliver irrigating fluid to the wound bed.

3. A vacuum wound care module comprising:

a fluid reservoir;
 a pump module fluidly connected to the irrigation reservoir and adapted for pumping fluid out of the fluid reservoir;
 a venturi vacuum fitting fluidly connected to the pump module and having a vacuum outlet and a fluid outlet;
 a fluid connection from the fluid outlet to the fluid reservoir;
 a trap reservoir fluidly connected to the vacuum outlet; and
 a second fluid connection that is one of:

- (a) fluidly connected to the trap reservoir and (i) adapted to be fitted with a wound dressing to provide vacuum and allow removal of wound exudate or (ii) fitted to such a wound dressing such that, when the wound dressing is employed, it provides vacuum and allows removal of wound exudate, and
- (b) adapted to be fluidly connected to the trap reservoir and fitted to such a wound dressing such that, when the wound dressing is employed, it provides vacuum and allows removal of wound exudate.

4. The vacuum wound care module of claim 3, wherein the second fluid connection is according to (a).

5. The vacuum wound care module of claim 3, wherein the second fluid connection is according to (b).

6. The vacuum wound care module of claim 3, further comprising:

a diverting valve situated in the first fluid connection, the valve operating between (i) a position that directs fluid from the fluid outlet and the fluid reservoir and (ii) a position that directs a major portion of fluid from the fluid outlet and the fluid reservoir and a minor portion to a third fluid connection; and
 the third fluid connection that is one of

- (A) fluidly connected to the diverting valve and (i) adapted to be fitted with a wound dressing to provide fluid to the wound or (ii) fitted to such a wound dressing such that, when the wound dressing is employed, it provides such fluid, and
- (B) adapted to be fluidly connected to the diverting valve and fitted to such a wound dressing such that, when the wound dressing is employed, it provides such fluid.

7. The vacuum wound care module of claim 6, wherein the third fluid connection is according to (A).

8. The vacuum wound care module of claim 6, wherein the third fluid connection is according to (B).

9. A vacuum wound dressing for covering a wound bed comprising:

a wound contact layer comprising a fibrous blend or fibrous material that forms a cohesive gel when wetted by wound exudate;
 a source of vacuum situated to be separated from the wound bed by the wound contact layer; and
 a vacuum sealing layer covering the wound contact layer and adapted to retain relative vacuum in the wound contact layer, wherein (ii) the vacuum sealing layer comprises as an outer layer a foam layer.

10. The vacuum wound dressing of claim 9, further comprising:

a source of irrigating fluid situated to deliver irrigating fluid to the wound bed.

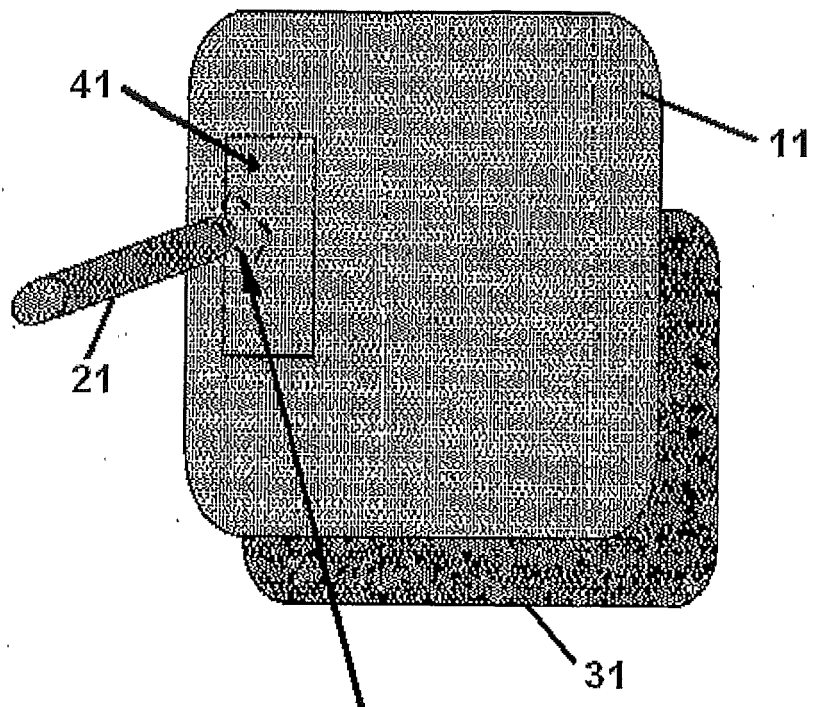


Fig. 1a

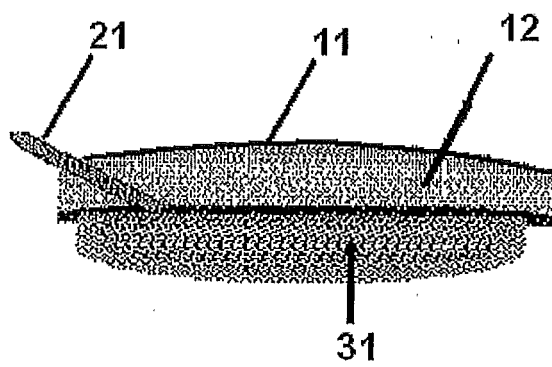


Fig. 1b

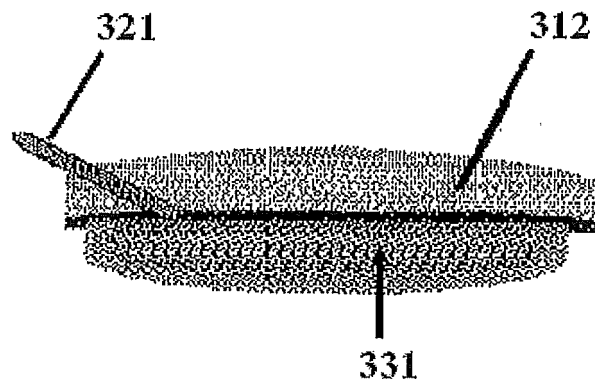


Fig. 2

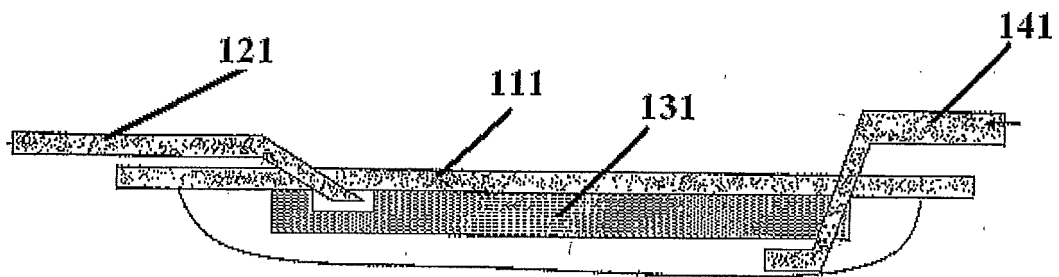


Fig. 3

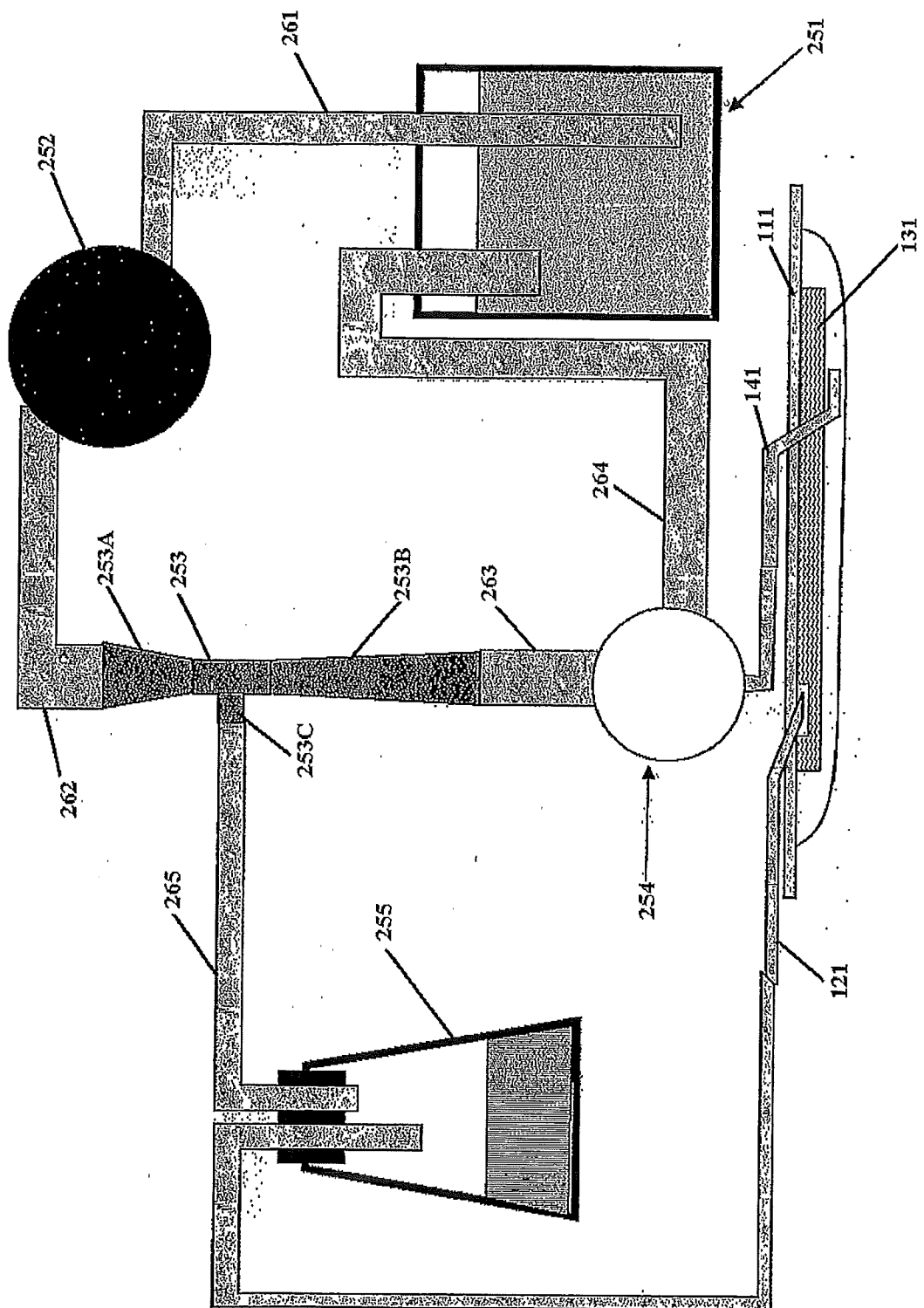


Fig. 4



EUROPEAN SEARCH REPORT

Application Number

EP 21 20 3237

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1 The present search report has been drawn up for all claims			
Place of search The Hague		Date of completion of the search 27 January 2022	Examiner Huyge, Kevin
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	

EPO FORM 1503 03.82 (P04C01)



EUROPEAN SEARCH REPORT

Application Number

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Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
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Application Number

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CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing claims for which payment was due.

☐ Only part of the claims have been paid within the prescribed time limit. The present European search report has been drawn up for those claims for which no payment was due and for those claims for which claims fees have been paid, namely claim(s):

☐ No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for those claims for which no payment was due.

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

see sheet B

☐ All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.

☒ As all searchable claims could be searched without effort justifying an additional fee, the Search Division did not invite payment of any additional fee.

☐ Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:

☐ None of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims:

☐ The present supplementary European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims (Rule 164 (1) EPC).



LACK OF UNITY OF INVENTION SHEET B

Application Number

EP 21 20 3237

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. claims: 1-10

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1.1. claims: 1, 2, 9, 10

A vacuum wound dressing for covering a wound bed comprising: a wound contact layer comprising a fibrous blend or fibrous material that forms a cohesive gel when wetted by wound exudate; a source of vacuum situated to be separated from the wound bed by the wound contact layer; and a vacuum sealing layer covering the wound contact layer and adapted to retain relative vacuum in the wound contact layer, wherein (i) the dressing is essentially missing a non-gelling, foam layer in which the source of vacuum is situated or (ii) the vacuum sealing layer comprises as an outer layer a foam layer.

1.2. claims: 3-8

A vacuum wound care module comprising: an fluid reservoir; a pump module fluidly connected to the irrigation reservoir and adapted for pumping fluid out of the fluid reservoir; a venturi vacuum fitting fluidly connected to the pump module and having a vacuum outlet and a fluid outlet; a fluid connection from the fluid outlet to the fluid reservoir; a trap reservoir fluidly connected to the vacuum outlet; and a second fluid connection that is one of:

(a) fluidly connected to the trap reservoir and (i) adapted to be fitted with a wound dressing to provide vacuum and allow removal of wound exudate or (ii) fitted to such a wound dressing such that, when the wound dressing is employed, it provides vacuum and allows removal of wound exudate, and

(b) adapted to be fluidly connected to the trap reservoir and fitted to such a wound dressing such that, when the wound dressing is employed, it provides vacuum and allows removal of wound exudate.

Please note that all inventions mentioned under item 1, although not necessarily linked by a common inventive concept, could be searched without effort justifying an additional fee.

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 21 20 3237

5 This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

**ANNEX TO THE EUROPEAN SEARCH REPORT
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